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In re application of: DANIEL R. KURZ
Entitled: INTRAVASCULAR DEVICE PUSH WIRE DELIVERY SYSTEM
Appln. No. 09/625,627
Filed: July 25, 2000
Date Mailed: February 12, 2001
Client ID/Dkt. No. MICRU-55322
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Application Number	09/625,627
Filing Date	July 25, 2000
First Named Inventor	Daniel R. Kurz
Group Art Unit	3731
Examiner Name	W. Lewis
Total Number of Pages in This Submission: 9	Attorney Docket Number: MICRU:55322

ENCLOSURES *(check all that apply)*

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PATENT
Atty. Docket No. MICRU-55322

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: W. Lewis
DANIEL R. KURZ	Group Art Unit 3731
Serial No. 09/625,627	CERTIFICATE OF MAILING
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Date: February 12, 2001	James W. Paul, Reg. No. 29,967 Attorney for Applicant

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The information listed on the attached PTO/SB/08A has come to the attention of the applicant and is submitted to the Office under 35 U.S.C. §§ 1.97 and 1.98. A copy of the reference listed is enclosed for the Examiner's consideration.

The Examiner is respectfully requested to consider and cite the enclosed reference as well as the earlier identified references in the prior Information Disclosure Statements.

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Sheet 1 of 1

Complete if Known	
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Filing Date	July 25, 2000
First Named Inventor	Daniel R. Kurz
Group Art Unit	3731
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Attorney Docket Number	MICRU-55322

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		RETRIEVABLE GIANTURCO-COIL INTRODUCER, By Jeffrey Hawkins, Ronald G. Quisling, MD, J. Parker Mickle, MD an Irvin F. Hawkins, MD (Radiology 1986) From the Depts. Of Radiology and Neurosurgery, University of Florida Medical Center and Hawk Prototype Equipment, Gainesville, FL	

Examiner Signature		Date Considered	

Discussion

A technique for arterial embolectomy using a balloon embolectomy catheter was first introduced in 1963 (1), and this technique has become recognized as the primary treatment for recent emboli in the lower extremities. We recommend the percutaneous use of this technique as an alternative to thrombolytic therapy (2, 3), catheter aspiration techniques (2, 4), or surgical embolectomy when PTA is complicated by embolism. The risk of subintimal passage of a balloon catheter in a recently dilated artery was thought to be reduced using this technique with physiologic arterial pressure distending the vessel; during these procedures there was no resistance to antegrade passage of the embolectomy catheters. Care was taken not to overdistend the balloon in the recently dilated arterial segment when retrieving the emboli. A large arterial sheath (9 F) was used to accept the emboli and inflated balloon. Since these procedures were performed, we have used an open-ended sheath with a Y-shaped rotating hemostatic valve (Advanced Cardiovascular Systems, Mountain View, Calif.) to retrieve emboli without having to cut and replace the sheath. Embolectomy should be more effective than thrombolytic therapy when PTA is complicated by atheroemboli on which thrombosis forms. Fogarty embolectomy catheters are frequently used without fluoroscopy during surgery. However, the tips of these catheters can be seen with fluoroscopy, and they are used more efficiently with fluoroscopy and arteriography. Dilated superficial femoral arteries were widely patent by arteriography at the end of the embolectomy procedures, although the potential adverse effects of balloon embolectomy on long-term patency of recently dilated arteries is unknown. We do not recommend the percutaneous use of balloon embolectomy catheters in situations where standard surgical embolectomy and/or vascular reconstruction is established treatment. ■

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Retrievable Gianturco-Coil Introducer[1]

Jeffrey Hawkins
Ronald G. Quisling, MD
J. Parker Mickle, MD
Irvin F. Hawkins, MD

A new delivery system for placement of Gianturco coils has been devised that permits retrieval of the coil if malposition occurs. The delivery system itself consists of a very fine coaxial cannula that will cut the monofilament once the coil is properly placed. It has been successfully used on three patients in whom a total of 48 coils were employed to occlude great vein of Galen aneurysms. The system is applicable for routine coil embolization but has particular application in treating high-flow vascular lesions (arteriovenous fistulas or malformations).

Index terms: Arteries, therapeutic blockade • Veins, Galen, 1765.73 • Veins, therapeutic blockade

Radiology 1986; 158:262–264

TREATMENT of high-flow arteriovenous fistulas requires tailoring of the methods to fit the characteristics of the target. Use of intravascular steel-Dacron coils has become accepted practice for many lesions (1–4). Treatment of high-flow fistulas associated with a vein of Galen aneurysm has proved especially difficult both for interventional neuroradiographic techniques and for direct surgical excision. To approach such lesions from the venous side of the fistula, a specialized introducer was needed that would allow the operator to retrieve the embolized coil if it could not be positioned optimally within an aneurysm in the vein of Galen. This particular application spurred the development of this coil-introducing system. It should be stressed that this procedure is still in the early stages of investigation. The risks inherent in the transtorcular treatment of high-flow fistulas are as yet unknown since this approach has been used in only a few patients. Venous occlusion of other high-flow states such as carotid-cavernous fistulas, however, has been highly successful without producing significant morbidity.

Materials and Methods

Technical description.—This device uses a 16-cm-long intravascular embolization steel coil of the Gianturco type (Cook Inc., Bloomington, Ind.) loaded within a 20-cm metal sheath. Fitting inside the coil loader is a specialized coaxial introducer system composed of a 25-gauge inner cannula to which is added a distal cutting block. Fitting around this is a 21-gauge outer cannula, the distal margin of which has cutting capability. A monofilament (4-lb test, 0.008 inch) passes through the inner cannula exiting via a side hole located just proximal to the cutting block. The monofilament is attached to the Gianturco coil. Retraction of this monofilament allows an already extruded coil to be returned to the sheath and ultimately to the loading cannula from which it can easily be repositioned or removed.

Technique.—A percutaneous puncture of a vessel is made, and a guide wire is positioned at the target. A 6.5-F polyethylene sheath catheter is placed over the guide wire and positioned optimally for embolization. The introducer system is passed through a Touhy-Borst adaptor. The coil-loading portion of the cannula stops in the hub of the catheter. The thinner metal coaxial cannulas, which contain the monofilament attached to the coil, are then pushed inward forcing the coil out of the embolization catheter and into the target. The embolization catheter should always be advanced as closely as possible to the target site. If the embolized coil moves away from the target or into an inappropriate position, retraction of the monofilament results in return of the coil to the catheter sheath. When the coil is correctly placed, the outer cannula is unlocked and rotated, which results in its moving forward and transecting the monofilament. The entire introducer system is then removed,

[1] From the Departments of Radiology (R.G.Q., I.H.) and Neurosurgery (J.P.M.), University of Florida Medical Center and Hawk Prototype Equipment (J.H.), Gainesville, Fla.

Received February 14, 1985; accepted and revision requested April 9; revision received May 10.

Address reprint requests to R.G.Q., Department of Radiology, Box J-374 JHMHC, Gainesville, FL 32610

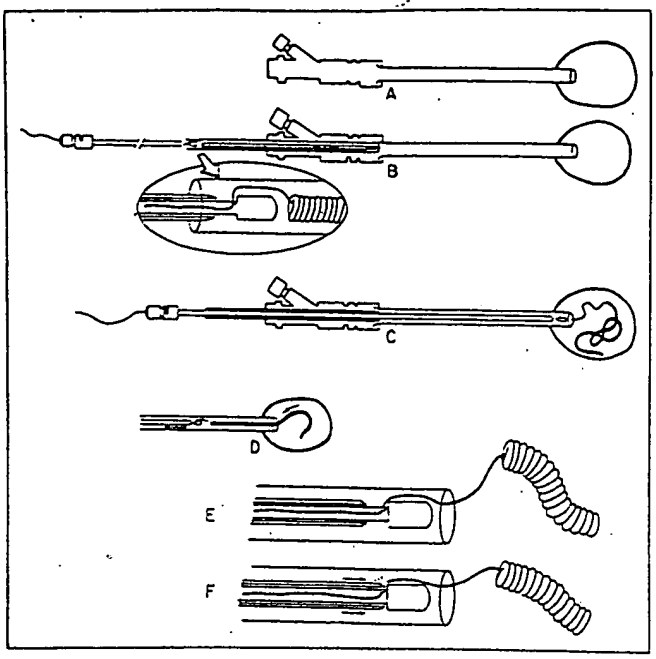


Figure 1. Embolization procedure. (A) The polyethylene embolization catheter is fluoroscopically directed into the target (circle). It has a Touhy-Borst adapter proximally to minimize blood loss during the procedure. (B) The Gianturco-coil loader is first introduced into the embolization catheter and then advanced toward the target using the coaxial metal cannulas containing the monofilament. The insert demonstrates the relationship of the monofilament to the inner cannula, which has the cutting block attached, and the outer cannula with its distal cutting edge. The monofilament attaches to the posterior aspect of the Gianturco coil. (C) The coaxial catheter is used to push the coil out of the catheter into the target. (D) If the coil position is unsatisfactory, it can be returned by retraction of the monofilament. (E) If the coil position is satisfactory, the outer sleeve of the coaxial metal cannula is slipped over the inner sleeve until its cutting edge engages the cutting block. (F) A twisting motion is then made to cut the monofilament. After the monofilament is detached, the entire coaxial system is removed, and the next wire can be introduced through the embolization catheter, which has remained in place.

Figure 2. Lateral skull radiograph illustrates the postembolic state after modified Gianturco coils were deposited via a percutaneous approach into a vein of Galen aneurysm. Following percutaneous catheterization of the superior sagittal sinus, the outer catheter was manipulated into the straight sinus and subsequently into the vein of Galen. Embolization wires were introduced into the lumen of the vein of Galen aneurysm (solid arrow) and proximal straight sinus (open arrow) until a reduction in venous pressure was noted at the puncture site in the superior sagittal sinus. Prior to embolization, this patient had a thorough evaluation of the flow dynamics and morphologic features of this lesion with computed tomography and angiography. A return to more normal cerebral blood flow was documented by Doppler ultrasound studies of the deep jugular venous system. Following coil embolization, significant improvement was noted in the patient's clinical status.

leaving the embolization catheter in place (Fig. 1). Another coil can then be introduced depending on the change in vascular dynamics. After each wire was correctly positioned and detached, the natural tendency of the wires to expand provided the means to ensure that the coil would remain applied against the wall of the aneurysm. Since the aneurysms were larger in cross-sectional diameter than the straight sinus, there was no observed movement of the coils from the target to the straight sinus or torcula. In addition, the wires became entangled as more were introduced (Fig. 2). Eventually a wire mesh was created. These two factors ensured that the embolic wires would stay in the target and not undergo distal migration. As the embolization procedure continued, the distention of the exposed torcula was observed to decrease. This provided a direct means of monitoring the course and success of the procedure.

Table 1
Coil Deposition Staging

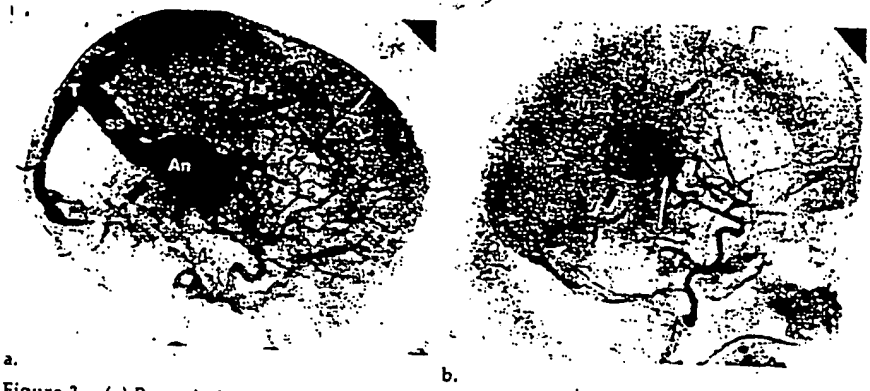
Patient No.	No. First Stage	No. Second Stage	Total
1	4	12	16
2	5	12	17
3	6	8	14

Results

A total of 48 coils were embolized successfully in three patients. The procedure was staged in all three cases. The distribution of coils is presented in Table 1. An initial embolization with approximately eight coils was used followed by additional embolization within 1 week for the remainder of the coils. During the embolizations, five coils were misdirected, entering thalamoperforating arteries. In each instance they were easily retrieved and subsequently repositioned before being detached. The monofilament was easily transected without dislodging the coil in all instances. Only minimal blood loss occurred during insertion of the coils. The coils either reduced flow or totally occluded the aneurysms in all three cases. Clinical details will be included in a subsequent publication.

Discussion

Certain high-flow vascular lesions, such as vein of Galen aneurysms, have proved to be particularly difficult to treat by either direct surgical approach or by interventional neuroradiographic means. Stainless steel coils and baffles have been used to control blood flow in a variety of other lesions, both in clinical practice and under experimental conditions (2–4). There is always the danger of coils passing through a high-flow fistula and embolizing the pulmonary circulation (5). To detect inadvertent migration of embolized wires prior to their release, a specialized introducer system was devised that maintains continuity with an embolized coil via a nylon monofilament. In the three clinical cases, migration of the coils into the confluence of venous sinuses (torcula) could have acutely raised intracranial pressure. The use of this system ensured stability of the coil prior to severing the monofilament and thereby avoided coil movement into the torcula. This device allowed assessment of the status of the coil within the embolization target prior to irrevocable release. It is also extremely important to detach the monofilament without moving the coil. The present system transects the monofilament without retract-



a. b.

Figure 3. (a) Preembolization lateral projection carotid angiogram demonstrates filling of the vein of Galen aneurysm (*An*), as well as ectasia of the straight sinus (*ss*) and a high position of the torcula herophile (*T*). The arteriovenous malformation associated with the venous abnormality is imaged as the capillary tangle of vessels surrounding the anteroinferior aspect of the vein of Galen aneurysm. (b) Postembolization lateral projection carotid angiogram obtained 3 months after embolic treatment with this Gianturco-coil introducing system demonstrates no filling of the vein of Galen aneurysm or straight sinus. A small residual vascular malformation persists (arrow), which subsequently fills into choroidal veins. A substantial portion of the vascular malformation, as well as the vein of Galen aneurysm, has been eradicated by the coil embolization. The mass of wires is apparent within the vein of Galen and proximal straight sinus region (compare with a).

ing it, thereby preventing positional changes of the coil within the target or precipitating migration from the nontarget area. The present system is moderately flexible with an ability to negotiate an approximately 90° turn within the outer embolization catheter. Clinical use to date has not required significant bending of the cannulas. For general vascular embolization, however, a more flexible system may be required. Presently, the same principle is being adapted to a guide wire system that will be as flexible as a standard 0.035 guide wire.

It should be noted that a transtorcular approach to such high-flow fistulas has not been considered a feasible alternative. However, use of vascular balloon catheters for high-flow fistulas such as carotid-cavernous fistulas has proved to be highly successful. In this instance, the balloon occludes a major dural sinus. The chronic nature of such a high-flow state alters the dependence of the cranial circulation to that particular route. This has become evident with the extensive intraarterial balloon occlusion work (6). The transtorcular venous catheterization and embolization for vein of Galen fistulas were carefully monitored during the procedure for venous pressure and clinical status. Additionally, the procedure was staged into two parts (Fig. 3). Partial occlusion was achieved first, and the subsequent embolization was used for final completion of the venous occlusion. Blood flow was monitored after each procedure and in the subsequent follow-up period by Doppler ultrasound. ■

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Application Number	09/625,627
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Examiner Name	W. Lewis
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